IN THE DRAWINGS

Filed concurrently herewith is a Drawing Amendment in which applicants request that Fig. 3 be amended as indicated. Applicants respectfully submit that the specification as originally filed with the USPTO clearly discusses Fig. 3, and specifically, that the "generally flat skin engaging surface 46 extend[s] in a plane that is generally perpendicular to the axis of the needle cannula 36 within about fifteen degrees of perpendicular or more preferable within about five degrees." See, e.g., paragraphs 0041 through 0044, inclusive. Thus, applicants submit that no new matter is added by the proposed drawing amendment.

IN THE SPECIFICATION

Please substitute paragraphs 0011, 0016, 0042, 0044 and 0052 as provided below, for paragraphs 0011, 0016, 0042, 0044 and 0052 currently in the present application.

[0011] Also, in the preferred embodiment of the assembly, the limiter portion and the hub portion are integrally formed as a single component, with the needle cannula fixedly attached to the hub portion of the single component behind the skin engaging surface of the limiter portion, with the hub portion including a throat for receiving the prefillable container and with the needle cannula fixedly attached to the hub portion with an adhesive. In addition, the skin engaging surface comprises a rigid polymer having an elastomeric central area with the needle cannula extending therethrough. Further, the substance includes an influenza vaccine. Still further, the needle assembly is attachable to a prefillable container with a Luer fit.

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[0016] In addition, in the preferred embodiment, the skin engaging surface ~~comprises a~~ rigid polymer having an elastomeric central area with the needle cannula extending therethrough,

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and needle assembly is attachable to a prefillable container with a Luer fit. Also, a sleeve circumscribes the limiter and is slidable for shielding the forward tip subsequent to administering an intradermal injection, with the limiter including at least one ramp allowing the limiter to be moved toward the forward tip and preventing the limiter from being moved away from the forward tip upon shielding the forward tip. The assembly may also include a tip cap removably affixed to the skin engaging surface and having the forward tip received therein. Further, the limiter may include a needle plunger slidably received thereby and oriented generally perpendicular to the axis of the needle cannula, with the needle plunger preferably depressable thereby bending the needle cannula and retracting the needle cannula into the limiter for shielding the forward tip subsequent to administering an injection. In addition, a forward cap is matable to a rearward cap wherein the caps enclose the needle assembly therebetween, with the forward cap and the rearward cap forming a sterile enclosure for storing the needle assembly.

[0044] The limiter portion 12 surrounds the needle cannula 36 and extends away from the hub portion 14 toward the forward tip 42 of the needle cannula 36. The limiter portion 12 includes an opening or aperture 48 which closely receives the needle cannula 36 and a generally flat skin engaging surface 46 extending in a plane 146 that is generally perpendicular to the axis of the needle cannula 36 within about fifteen degrees of perpendicular or more preferable within about five degrees. The skin engaging surface 46 is adapted to be received against the skin of the animal to administer an intradermal injection of the substance. The skin engaging surface 46 is represented as being generally flat and continuous and provides for a stable placement of the needle assembly 10 against the animal's skin. Referring to Figure 6A, the skin engaging surface may include an annular groove 47 with a central surface 49 circumscribing the needle cannula.

Figure 6B shows a skin engaging surface 46 having a plurality of spokes 51 projecting outwardly from the central surface 49 in a plane generally parallel to that of the central surface 49. The skin engaging surface 46 provides stability for the device during injection and preferably has a cross-section of at least 5 mm or between 5 to 20 mm.

[0042] The needle cannula 36 includes a rearward needle end 40 that extends through the sheath 34 into the throat 18 of the hub portion 14. When the prefillable container 20 is inserted into the throat 18 the rearward needle end 40 is in fluid communication with the prefillable container 20 thereby allowing the substance disposed within the prefillable container 20 to be expelled through the needle cannula 36. Preferably, the prefillable container 20 will be inserted into the throat 18 just prior to administering the intradermal injection. The rearward needle end 40 may be extended and pointed (not shown) to be able to pierce the sealed prefillable container making the fluid connection. The throat 18 includes a tapered bottom 21 adapted to retain the inserted prefillable container 20 through a Luer Slip connection as is well known in the art of syringe retention. Alternatively, a Luer Lok connection (not shown) may be utilized to retain the prefillable container 20 within the throat 18.

[0052] As will now be understood, the intradermal delivery device 10 of this invention includes a needle enclosure means, which encloses or conceals the needle cannula tip 42 following injection and which preferably cannot be retracted to prevent accidental needle contact or reuse. In one embodiment shown in Figures 7 and 8, the assembly includes an extendable shield 312, which locks in the extended position, preventing contact with the needle cannula 36. In another embodiment shown in Figures 9 and 10, the needle cannula 36 is bent or deformed